Ion Chromatography Method for Determination of Dimethyl Sulphate Content in lornoxicam Drug Substance with Suppressed Conductivity Detection

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ABSTRACT

A simple and sensitive ion chromatography method has been developed for the determination of dimethyl sulphate content in Lornoxicam drug substance. Efficient chromatographic separation was achieved on IonPac AS10, anion column 250 mm long with 4 mm i.d., 8.5 μ m particle diameter. Mobile phase consists of 2.7mM Na₂CO₃ + 0.3mM NaHCO₃. The mobile phase was delivered in an isocratic mode at a flow rate of 1.5 mL/min at ambient temperature conditions and the analyte was monitored by conductometric detector. The method was validated for specificity, precision, linearity, solution stability and accuracy. The limits of detection (LOD) and limits of quantification (LOQ) established for dimethyl sulphate are 1.60 ppm and 3.85 ppm respectively. The average recoveries for dimethyl sulphate are in the range of 103.4 % -105.3 % and the method can be successfully applied for the routine analysis of Lornoxicam Drug substance.